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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/672,937

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Timothy B. Stockwell

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EXAMINER

ZHOU, SHUBO

ART UNIT

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1631

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/672,937	Applicant(s) STOCKWELL ET AL.	
	Examiner Shubo (Joe) Zhou	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/10/08.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13-16, 18 and 45-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13-16, 18, and 45-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

RCE

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/10/08 has been entered.

Claims 1-11, 13-16, 18, and new claims 45-47 are currently pending and under consideration.

Applicant's arguments filed 1/10/08 in response to the previous Office action have been fully considered but they are not deemed to be persuasive. The following rejections and/or objections are reiterated from the previous Office action or newly applied but necessitated by applicant's amendments, and constitute the complete set presently being applied to the instant application. Rejections and/or objections not reiterated from the previous Office action are hereby withdraw

Claim Rejections-35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

New claim 47 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

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Claim 47 is drawn to a computer readable medium comprising computer instructions. While the instant specification does not explicitly define the scope of the limitation of "computer readable medium," one skilled in the art would understand that computer readable medium includes carrier wave, which is a signal. For example, Fiekowsky et al., in US patent 6,090,555 (Date of Patent: July 18, 2000), define computer readable medium as being "a CD-ROM, floppy disk, tape, flash memory, system memory, hard drive, and a data signal embodied in a carrier wave." See column 14, claim 12. Bornstein et al., in US patent 6,1443,88 (Date of patent : Nov. 7, 2000) state, "The computer readable medium of the present invention generally includes a tape, a floppy disk, a CD ROM, a carrier wave. In a preferred embodiment, however, the computer readable medium of the present invention is a carrier wave." See column 8, lines 33-37.

Therefore, at least one embodiment of the instant claim is drawn to a carrier wave or a signal encoded thereon a computer program.

It was held by the court that claims that recite nothing but the physical characteristics of a form of energy, such as a frequency, voltage, or the strength of a magnetic field, define energy or magnetism, per se, and as such, are nonstatutory natural phenomena. O'Reilly, 56 U.S. (15 How.) at 112-14. Moreover, it does not appear that a claim reciting a signal encoded with functional descriptive material, e.g. a computer program, falls within any of the categories of patentable subject matter set forth in § 101. The following analysis on why such a signal encoded with functional descriptive material is nonstatutory subject matter is excerpted from the US PTO's "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter

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Eligibility" (OG Notices: 22 November 2005, available from the US PTO website at

<http://www.uspto.gov/web/offices/com/sol/og/2005/week47/og200547.htm>):

First, a claimed signal is clearly not a "process" under § 101 because it is not a series of steps. The other three § 101 classes of machine, compositions of matter and manufactures "relate to structural entities and can be grouped as 'product' claims in order to contrast them with process claims." 1 D. Chisum, Patents §1.02 (1994). The three product classes have traditionally required physical structure or material.

"The term machine includes every mechanical device or combination of mechanical device or combination of mechanical powers and devices to perform some function and produce a certain effect or result." Corning v. Burden, 56 U.S. (15 How.) 252, 267 (1854). A modern definition of machine would no doubt include electronic devices which perform functions. Indeed, devices such as flip-flops and computers are referred to in computer science as sequential machines. A claimed signal has no physical structure, does not itself perform any useful, concrete and tangible result and, thus, does not fit within the definition of a machine.

A "composition of matter" "covers all compositions of two or more substances and includes all composite articles, whether they be results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids." Shell Development Co. v. Watson, 149 F. Supp. 279, 280, 113 USPQ 265, 266 (D.D.C. 1957), aff'd, 252 F.2d 861, 116 USPQ 428 (D.C. Cir. 1958). A claimed signal is not matter, but a form of energy, and therefore is not a composition of matter.

The Supreme Court has read the term "manufacture" in accordance with its dictionary definition to mean 'the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery.' Diamond v. Chakrabarty, 447 U.S. 303, 308, 206 USPQ 193, 196-97 (1980) (quoting American Fruit Growers, Inc. v. Brogdex Co., 283 U.S. 1, 11, 8 USPQ 131, 133 (1931), which, in turn, quotes the Century Dictionary). Other courts have applied similar definitions. See American Disappearing Bed Co. v. Arnaelsteen, 182 F. 324, 325 (9th Cir. 1910), cert. denied, 220 U.S. 622 (1911). These definitions require physical substance, which a claimed signal does not have. Congress can be presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it re-enacts a statute without change. Lorillard v. Pons, 434 U.S. 575, 580 (1978). Thus, Congress must be presumed to have been aware of the interpretation of manufacture in American Fruit Growers when it passed the 1952 Patent Act.

A manufacture is also defined as the residual class of product. 1 Chisum, § 1.02[3] (citing W. Robinson, The Law of Patents for Useful Inventions 270 (1890)). A product is a tangible physical article or object, some form of matter, which a signal is not. That the other two product classes, machine and composition of matter, require physical matter is evidence that

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a manufacture was also intended to require physical matter. A signal, a form of energy, does not fall within either of the two definitions of manufacture. Thus, a signal does not fall within one of the four statutory classes of § 101.

[.....]

These interim guidelines propose that such signal claims are ineligible for patent protection because they do not fall within any of the four statutory classes of § 101. Public comment is sought for further evaluation of this question.

Thus, claim 47 is drawn to nonstatutory subject matter.

Claim Rejections-35 USC § 112

The following is a quotation of the **second** paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11, 13-16, 18, and new claims 45-47 are rejected under 35 U.S.C. 112 , second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites “trimming the consensus sequence information until the percentage of ambiguous bases is below a user-defined threshold to form trimmed consensus sequence information.” The metes and bounds of the limitation are not clear. One skilled in the art would understand that trimming means, for a nucleic acid sequence, shortening the sequence from the ends. However, if the ambiguous bases are present in the middle of the sequence, one skilled in the art would not know how the trimming would be done.

Claim 1 recites determining "variant information between the trimmed consensus sequence information and the reference sequence information" and outputting the variant information to a user. The metes and bounds of the limitation “variant information” are not clear

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because it is unclear what information is comprised. For instance the “variant information” could include the length, sequence, percentage of each different base, melting point, etc. It is not clear whether the “variant information” determined and outputted include all these or only the sequence.

Claim 47 is rejected for the same reasons set forth above for claim 1.

Claims 13-15 recite “consecutive runs of bases.” The metes and bounds of the limitation are not clear because it is unclear whether it means consecutive runs of the same bases such as AAAA or GGGG, or it also includes consecutive runs of certain type of bases, e.g. AGAGAG, which is a consecutive run of purines.

Claim 14 recites “[t]he method of claim 13, wherein the empirical threshold for comparing consecutive runs of bases” The phrase “the empirical threshold for comparing consecutive runs of bases” lacks clear antecedent basis because there is no prior reference in claim 13 for an empirical threshold for comparing consecutive runs of bases.

Claim 15 recites “the generated rule-based criteria further comprises identifying consecutive runs of bases” The metes and bounds of the limitation are not clear because it is unclear how rule-based criteria could comprise a step of identifying consecutive runs of bases as in other claims and in the specification, the rule-based criteria comprise rules (see claim 1).

Objection, Warning

Applicant is advised that should claim 7 be found allowable, claim 10 will be objected to under 37 CFR 1.75 as being substantial duplicates thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight

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difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). In the instant case, the two claims are identical in scope.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Shubo (Joe) Zhou/

SHUBO (JOE) ZHOU, PH.D.

PRIMARY EXAMINER